ied across GLP-1RAs and analyses (ranging from 2.162 [p<0.001] for exenatide vs. exenatide QW among initial adherers, to 0.986 [p=0.798] for liraglutide 1.8mg vs. exenatide QW among initial adherers, to 0.869 [p<0.001] for liraglutide 1.8mg vs. exenatide QW among all patients). **CONCLUSIONS:** Among patients newly initiating exenatide QW, exenatide, or liraglutide, adherence was consistently highest for exenatide QW, while non-persistence varied by analyzed group.

PDB137
REVIEW OF THE USUAL TREATMENT OF ADULTS WITH TYPE 2 DIABETES IN JAPAN
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OBJECTIVES: The personal and economic burden of diabetes is substantial and growing in Japan due to its aging population. This study aimed to review the available literature on the usual treatment of adults with type 2 diabetes (T2DM) in Japan. **METHODS:** Systematic search of the scientific literature was performed on MEDLINE and EMBASE databases to identify publications about usual care of diabetes in Japan written in English or Japanese and published between January 2000 and May 2013. Included keywords were diabetes mellitus, drug therapy and Japan. Randomized clinical trials, comparative or interventional studies were excluded. Of 17 publications that met search criteria, 13 pertained to adults with T2DM, of which 9 contained original survey data and 4 were literature reviews. **RESULTS:** Almost all of the available data was at least 7 years old. Based on data from 2000 to 2002, the use of oral anti-diabetic drugs (OAD) alone was the most prevalent treatment option (51.4%), followed by diet alone (25.4%), insulin alone (15.4%), and OAD with insulin (7.8%). Although overall, sulfonylureas was the preferred class of OAD (61-67%), its use among treatment initiators has dramatically declined from 40% to 22% following the introduction of dipeptidyl peptidase-4 inhibitors (DPP4) in 2009. Since then, the prescription rate of DPP4 increased to nearly 40% due to its perceived better safety. **CONCLUSIONS:** Available data on the treatment of diabetes in usual care in Japan is rather sparse and not recent. Results indicate that the treatment of adults with T2DM in Japan with OAD and insulin is rather similar to that in the US and Europe, although the specific OAD in Japan is different. Further research is needed on the usual treatment of diabetes in Japan, considering increased longevity, lifestyle changes, ongoing introduction of new medications, changes in disease management practices and increased economic concerns.

PDB139
UNDER-DIAGNOSIS OF TYPE II DIABETES AMONG CHILEAN ADULT MEN: AN URGENT EQUITY ISSUE
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OBJECTIVES: Type II Diabetes Mellitus (DM) is exponentially growing in Chile. A recent reform aimed at reducing inequities in health care in the country, but the gap between social groups continues to grow. We aimed at exploring the existence of under-diagnosis of type II DM in adult population in Chile. **METHODS:** Secondary analysis of cross-sectional Chilean Health Survey 2009-2010 (n=4767 adults, weighted sample: 13,347,316). We compared the proportion of adult population self-reporting type II DM against the proportion with altered fasting glycaemia (value >126mg/dl, Chi-square test) and then assessed the socio-demographic characteristics of those having the condition but ignoring it. For population-representative analysis we used Stata 12.0. **RESULTS:** 48.7% sample were men, mean age was 42 years (s.d.:40.8), 56.9% had middle socioeconomic status (SES), followed by high and low (18.6%, 24.5%) and 87% lived in urban areas. A 7.8% reported being diagnosed with type II DM. There was a significantly higher rate of self-reported DM among women than men (5.0% versus 2.8%) and people living in urban versus rural settings (6.7% and 1.0%). People with self-reported DM were on average 17 years older than people without previous diagnosis (mean:57.1). According to lab results, 8.4% of the total adult population had type II DM. From this group, over half (4.6%) had not been diagnosed with this condition before, representing over 280,000 people. They are mostly middle-aged men (mean age:46.6) from low and middle SES and living in urban areas. **CONCLUSIONS:** We found an under-diagnosis of type II DM among middle-aged male adults in Chile. Few recent studies report the urgent need to develop community-based strategies to enhance male use of health care, particularly to pursue screening consultations even when feeling healthy. This study supports such initiative and challenges the complex relationship between gender and SES, which could be further explored in Chile.

PDB140
OUT-OF-POCKET SPENDING AND FINANCIAL BURDEN OF PRESCRIPTION DRUGS FOR DIABETES: 2007-2010
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OBJECTIVES: To examine the changes in out-of-pocket spending and financial burden of prescription drugs for diabetes between 2007 and 2010. **METHODS:** The Medical Expenditure Panel Survey for 2007-2010 was analyzed for patients with diabetes. Out-of-pocket spending was defined as any self-reported coinsurance and deductibles, as well as payments for prescription medications that were not covered by insurance. Financial burden for prescription drugs was measured using the proportion of out-of-pocket expenditures divided by total family income in a given year. Expenditures for each year were adjusted using Consumer Price Index. **RESULTS:** The out-of-pocket spending for prescription drugs for treating diabetes was dropped significantly from $232.5 in 2007 to $197.9 in 2010, while the total expenditure for prescription drugs for diabetes increased dramatically from $875.9 to $1026.3 during the same period. This declined out-of-pocket spending was observed across different age, gender, and racial groups. From 2007 to 2010, the financial burden of prescriptions drugs for diabetes increased from 0.8% to 1.1%, which was largely driven by declined annual family income ($56,139 in 2007 to $52,811 in 2010). This increasing trend was observed particularly among diabetic patients with low family income (2.3% in 2007 to 5.0% in 2010). In the contrast, the financial burden of medications was relieved for those aged younger than 18 years old (1.8% in 2007 to 0.3% in 2010). Patients receiving insulins and thiazolidinediones had higher out-of-pocket spending as well as financial burden than those used other medications to treat diabetes. **CONCLUSIONS:** Patients' drug costs were reduced successfully between 2007 and 2010. However, the financial burden of prescription drugs for diabetes increased due to decreased family income. Since the use of prescription drugs is a vital part of diabetes management, more efforts should be directed to patients with low family income in order to improve affordability of prescription drugs.

PDB141
EXCESS HEALTH CARE EXPENDITURES ASSOCIATED WITH PRESENCE OF THYROID DISORDERS AMONG INDIVIDUALS WITH DIABETES: A COST-DECOMPOSITION ANALYSIS
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OBJECTIVES: To examine the relative contribution of predisposing, enabling, need, and external environment factors to the excess health care expenditures associated with thyroid disorders among individuals with diabetes, compared to individuals with diabetes and without thyroid disorders. **METHODS:** Cross-sectional study design with data on adults over 20 years of age with diabetes (N = 4,920) from two years (2009 and 2011) of the Medical Expenditure Panel Survey (MEPS) were used. Ordinary least square regressions on log-transformed total expenditures were performed to estimate the excess expenditures associated with thyroid disorders after controlling for predisposing, enabling, external environment, life-style and need factors as defined framework of the Anderson Behavior and Healthcare Utilization Model. Post-regression Blinder-Oaxaca (BO) decomposition analysis was performed to examine the relative contribution of factors in explaining the average differences in health care expenditures between the two groups. **RESULTS:** Among individuals with diabetes, those with thyroid disorders had greater annual mean expenditure compared to those without thyroid disorders ($ 14,289 *vs.* $10,636, p < 0.001). After accounting for the predisposing, enabling, external environment, life-style and need factors, those with thyroid disorders had 15% greater health care expenditures compared to those without thyroid disorders. The BO decomposition analysis revealed that predisposing, enabling, external environment, life-style and need factors explained 63% of the excess health care expenditures among individuals with thyroid disorders. The excess health care expenditures between the groups was predominantly explained by need-factors (43%). Presence of cardiovascular diseases, depression, arthritis, and cancer explained the excess expenditures between the groups among the need-factors. **CONCLUSIONS:** Presence of thyroid disorders is associated with greater health care expenditures among individuals with diabetes. Co-management of co-occurring conditions may reduce the excess health care expenditures among individuals with thyroid disorders and diabetes.

PDB143
DISABILITY ADJUSTED LIFE YEARS LOST DUE TO DIABETES IN FRANCE, ITALY, GERMANY, SPAIN AND THE UNITED KINGDOM: A BURDEN OF ILLNESS STUDY
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OBJECTIVES: To compare the burden of disease attributable to diabetes expressed in Disability Adjusted Life Years (DALYs) for five European countries in 2010. **METHODS:** DALYs lost to diabetes as the sum of years of life lost and years lived with disability were estimated by gender and age using country-specific epidemiological data and global disability weights. Data from various secondary sources were combined to estimate health loss due to diabetes for France, Germany, Italy, Spain and the UK. National statistical databases were used and in case necessary, community studies were used to derive the prevalence of diabetes by gender and age group which were weighted proportionately for a national population burden of disease estimate. All identified data were adapted to the Global Burden of Disease methodology (2010) to calculate the burden attributable to diabetes. No age weighting and discounting was applied. Sensitivity to different sources of variation was examined. **RESULTS:** Germany and Italy lost the largest number of DALYs due to diabetes with 5.9 and 5.8 per 1,000 inhabitants respectively, followed by Spain (4.4), France (3.7) and the UK (2.9). The highest burden was caused by mortality due to diabetes, with the exception of the UK, for which the burden due to disability of diabetes was higher. This may be explained by the way of reporting death in the UK. Mean DALYs lost were higher for women in Germany, Italy and Spain and showed to increase with age for all countries. Sensitivity analysis in variation in disability weights and uncertainty in epidemiological data showed to have effects on DALYs lost. **CONCLUSIONS:** In spite of data limitations, the estimates reported here show that DALY loss due to diabetes imposes a substantial burden on countries. Cross-national variation in disease epidemiology was the largest source of variation in the burden of diabetes between countries.

PDB144
MATHEMATICAL SIMULATIONS OF ALOGLIPTIN-PIOGLITAZONE-TREATED PATIENTS MEETING QUALITY ASSURANCE HBA1C THRESHOLD REQUIREMENTS
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OBJECTIVES: Alogliptin-pioglitazone (alo-pio) reduces HbA1c levels in treatment-naïve Type 2 diabetic (T2DM) patients, or those inadequately controlled by monotherapy. Yet, the percentage of patients on alo-pio continuing to meet HbA1c thresholds suggested by the National Committee for Quality Assurance (NCQA) is unclear but may be important to accountable care organizations (ACOs). This analysis examined whether NCQA recognition, aligning with >40% of patients below 7%, >60% below 8%, and ≤15% above 9% HbA1c, is achievable. **METHODS:**

Simulations estimated 1- and 3-year HbA1c progression for 1000 hypothetical T2DM patients (average 7 (SE 5.1) years post-diagnosis) to obtain the proportion meeting criteria for <7%, <8% and >9% thresholds by bootstrapping the UK Prospective Diabetes Study (UKPDS) 68 equation. UKPDS68 accounts for time, HbA1c in the prior year, drug treatment effect, and baseline A1c. Parameter values for duration of diabetes, baseline HbA1c, and treatment effect were selected from distributions around the mean, and mean values of the latter two were systematically varied to approximate different populations and effects. **RESULTS:** By 1 year, all NCQA requirements are met when treating patients with alo-pio if average baseline HbA1c is ≤8%. At 3 years, all requirements are met in patients with baseline HbA1c ≤7.2%, though 8% and 9% threshold requirements are feasible with higher baseline HbA1c. Using a more realistic thiazolidinedione durability assumption (annual rosiglitazone HbA1c increase) instead of UKPDS68, all thresholds are met at 1 year ≤8% baseline HbA1c, and at 3 years with ≤7.4% baseline HbA1c. The 7% and 8% requirements are met with ≤8.2% baseline HbA1c at 1 year; at 3 years, 8% and 9% thresholds can be met with baseline HbA1c ≤8-8.2%. **CONCLUSIONS:** The simulations show that clinical thresholds can be met at 1 and 3 years, indicating that alo-pio can be considered for treating an appropriate population from an ACO perspective.

PDB145

RELEVANCE OF CLINICAL TRIALS TO INFORM HTA: DISPARITY BETWEEN HTA EVIDENCE REQUIREMENTS AND PUBLISHED RCTS IN TYPE 2 DIABTETES MELLITUS

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OBJECTIVES: Health technology assessment (HTA) agencies and reimbursement authorities typically require evidence from randomised controlled trials (RCTs) to assess the comparative effectiveness of drugs. For example, for an assessment of the GLP-1 receptor agonist exenatide for management of Type 2 diabetes mellitus (T2DM), the German Federal Joint Committee (G-BA) pre-specified comparators of interest for short- (Byetta®) and long-acting exenatide formulations (Bydureon®) in seven indications. The aim of this research was to assess the availability of direct or indirect evidence for the benefit of exenatide to support an HTA submission to the G-BA. **METHODS:** A systematic literature review was conducted to identify RCTs comparing exenatide with pharmacological interventions in patients with T2DM. Electronic databases (Medline, Embase, Cochrane library: accessed October 2013) and clinical trial registries were interrogated. **RESULTS:** Of twenty-nine Byetta® RCTs identified, twenty-seven were inappropriate to provide evidence to the G-BA for the following reasons: use of a non-pre-defined comparator (n=13), background treatment not requested by G-BA (n=12), or administration of a non-licenced Byetta® dose (n=2). The remaining two studies provided direct evidence for two indications. None of the eight Bydureon® RCTs identified were appropriate for direct analysis: use of a non-G-BA-required background treatment (n=7) or comparator (n=1). For the five indications where no direct evidence was available, a single RCT investigating Bydureon® was identified which could potentially be used in an indirect comparison against a G-BA required comparator. **CONCLUSIONS:** Despite identification of over thirty RCTs investigating exenatide, most of the available evidence would not be considered appropriate by the G-BA to assess the benefit of exenatide despite having formed the basis for regulatory approval. Regulatory and HTA agencies, reimbursement authorities, and the pharmaceutical industry should be aligned on appropriate RCT design to ensure the generation of relevant evidence, although this may be challenging given the dynamic diabetes treatment environment.

PDB146

PATIENT AWARENESS OF HBA1C IN TYPE 2 DIABETES: TRENDS AND IMPLICATIONS FOR HEALTH OUTCOMES

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OBJECTIVES: Maintaining glycemic control for patients with type 2 diabetes (T2D) is associated with a reduced risk of future complications. Proper patient awareness of HbA1c is important to facilitate adherence and improve outcomes. This study profiles how HbA1c awareness has changed over time and the consequences of poor awareness. **METHODS:** Data from the 2006-2013 US National Health and Wellness Survey (NHWS) were used in the analysis (Ns = 62,834 to 75,000 in each year). The NHWS is an annual, patient-reported, cross-sectional survey fielded to match the demographic characteristics of the US adult population. Patient awareness of their HbA1c levels (i.e., a reported value vs. a "don't know" response) was examined each year. Differences between those who were aware versus unaware were made with respect to health status (using the SF-36v2), work productivity loss (using the WPAI-GH), and health care resource in a series of regression models controlling for demographics and health characteristics. **RESULTS:** Awareness of HbA1c levels improved from 26.6% (in 2006) to 56.4% (in 2013). In 2013, patients who are aware (n=4658) were more likely to be older (60.5 vs. 57.2 years), non-Hispanic white (71.4% vs. 61.1%), treating with oral/insulin/non-insulin injectable (87.8% vs. 76.1%), and more likely to have had diabetic complications compared with those who were unaware (n=3040; all p<.05). Holding demographics and health history constant, lack of awareness was associated with poorer health utilities (0.70 vs. 0.68), more overall work impairment (17.9% vs. 20.8%), and more hospitalizations in the past six months (0.26 vs. 0.22), among other outcomes (all p<.05). **CONCLUSIONS:** Awareness of HbA1c has increased over time, though appears disproportionately higher among patients of high socioeconomic status and higher risk (i.e., those with complications and using insulin). Awareness was also independently associated with poorer health outcomes suggesting improved patient education may have significant societal benefits.

PDB147

WHY PHYSICIANS DO NOT FOLLOW AACE/ACE GUIDELINES IN TREATING QUALIFIED PATIENTS WITH T2DM: A SURVEY STUDY IN THE UNITED STATES

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OBJECTIVES: To assess factors affecting physicians' decision on why they did not initiate dual therapy to untreated Type 2 Diabetes Mellitus (T2DM) patients with A1C 7.6–9% per AACE/ACE recommendation. **METHODS:** Primary care physicians (PCPs) and specialists in the US were asked to provide medical chart reviews for 4 patients who were diagnosed with A1C 7.6-9% and initiated with metformin monotherapy. Physicians rated 22 reasons on a 5-point Likert scale (1-most irrelevant; 5-most relevant) on how relevant each reason was for them in treating a specific patient. Top 5 reasons (≥50% of physicians rating the reason as 4 or 5) were identified. Association of each reason on physician specialty or age was conducted using mixed-effect model controlling for physician and patient characteristics. **RESULTS:** 1,235 PCPs and 290 specialists participated the study and provided reviews for 5,995 patients (3,009 young and 2,986 elderly). Four relevant reasons were related to physicians attitudes and beliefs toward metformin monotherapy and dual therapy: R1-"Metformin monotherapy is sufficient to improve glycemic control" (mean[sd]: 3.66[1.1]); R2 - "Monotherapy is easier to handle than dual therapy" (3.53[1.2]); R3- "I believe that monotherapy and changes in lifestyle (e.g. physical activity and dietary change) are enough for hyperglycemia control" (3.47[1.1]); and R4- "I recommend monotherapy before considering dual therapy" (3.75[1.1]). One relevant reason was related to physicians' perception of patients' glycemic level: R5 -"Patient has mild hyperglycemia" " (3.27[1.1]). PCPs rated the four reasons more relevant than specialists (estimate,[95% CI]) (R1: 0.18,[0.05,0.30]; R2: 0.37,[0.24,0.50]; R3: 0.33,[0.20,0.46]; R4: 0.36,[0.23,0.49]. All p<0.01). Lowering age was also more relevant in the four reasons (R1: -0.04,[-0.06,-0.02]; R2: -0.03,[-0.05,-0.02]; R3: -0.02,[-0.03,0.00], R4: -0.06,[-0.07,-0.04]. All p<0.02). **CONCLUSIONS:** Guideline non-concordance is related to physicians' attitudes and beliefs toward the therapies and perception of A1C above 8% as "mild". The findings have implications for improving T2DM treatment quality.

PDB148

LONGITUDINAL PATTERNS OF ANTIDIABETES MEDICATION PRESCRIPTION AMONG PRIVATELY INSURED MEDICARE PATIENTS

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OBJECTIVES: To describe changing diabetes treatment pattern among the elderly type 2 diabetes (T2DM) patients during the past 7 years. **METHODS:** A large retrospective Medicare patient claims data (MarketScan® Medicare) was longitudinally analyzed from 2005 to 2011 to understand T2DM medication use trend. The study included 4 major oral antidiabetic medications (i.e., metformin (MET), sulphonylurea (SU), thiazolidinediones (TZD), and dipeptidyl peptidase 4 inhibitor (DPP-4)) plus injectables (insulin and glucagon-like peptide 1 (GLP-1)) and reported patterns of therapy regimens and trends over time. **RESULTS:** The study identified 453,045 patients with 1 year enrollment and with T2DM taking one or more antidiabetic medications in 2011, compared to 283,484 patients in 2005. The frequently used mono therapies in 2011 are MET (22.1%), insulin (12.0%) and SU (10.8%), followed by TZD (2.6%), DPP-4 (2.0%), GLP-1 (0.28%). The percentage of patients using MET monotherapy increased from 15.0% in 2005 to 22.1% in 2011, while the percentage of patients using SU alone decreased from 16.6% in 2005 to 10.8% in 2011. Patients taking DPP-4 only increased from 0.03% in 2006 to 2.0% in 2011. Among the combination therapies in 2011, the most popular one was MET+SU (12.2%), followed by MET+DPP-4 (2.9%), MET+SU+DPP-4 (2.8%), MET+TZD (2.8%) and MET+SU+insulin (2.3%). The percentage of patients taking any type of insulin rose by 3.4 on from 24.7% in 2005 to 28.1% in 2011. **CONCLUSIONS:** This study shows changing trends in different classes of diabetes medication in this large sample Medicare patients over time. Continuing research is needed to monitor anitdiabetic treatment pattern change in the future and to understand how these changes are helping to improve diabetes care and outcomes.

PDB149

MEDICATION ADHERENCE AND SWITCHING RATES OF PATIENTS WITH TESTOSTERONE REPLACEMENT THERAPY (TRT) IN THE UNITED STATES

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OBJECTIVES: To assess medication adherence and switching rates of testosterone replacement therapy (TRT) in the US. **METHODS:** We conducted a retrospective claims database study using the MarketScan® Commercial database from January 2005 through December 2011. The study included men 18-65 years of age who had initiated TRT and were diagnosed with hypogonadism or hypogonadotropic hypogonadism (ICD-9-CM: 257.3 and 257.4). A minimum of 6 months continuous enrollment before and 12 months after the TRT index date was required. Adherence was measured by the Mediation Possession Ratio (MPR) and the Proportion of Days Covered (PDC), with the adherence rate defined as MPR≥0.8. The rate of the first switching was summarized by TRT formulation. **RESULTS:** Of 106,039 patients with hypogonadism, the mean MPR and the mean PDC of any TRT during the 360 days study period was 0.47 and 0.44, respectively. The overall adherence rate over 12 months was 21.4% ranging from 28% (pellets), 19.9% (SAIs), 17.7% (gels), 7.8% (buccal), and 6.6% (patch), respectively. Similarly, the average PDCs were significantly higher for pellets (0.59) compared to gels (0.43), SAIs (0.39), buccal (0.28), and patch (0.27) (P<0.001). About 13% (n = 13,577) of patients switched from their initial therapy to a different TRT formulation. Patients starting with patch were most likely to switch to a different formulation (39.3%), followed by patients with SAIs (12.1%), pellets/buccal (12.0%), and gels (10.3%). **CONCLUSIONS:** Our study showed low adherence rates of testosterone replacement therapy among hypogonadism patients. The adherence for patients starting on the long-acting testosterone formulation such